



ENZYMATIC THERAPY
INCORPORATED

*What **Better** feels like.™*

INTEGRATIVE THERAPEUTICS INC.™
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Tyler Encapsulations ♦ Vitaline Formulas

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Wilsonville, OR 97070
P: 503.582.8386 ♦ F: 503.582.0467

ENZYMATIC THERAPY®
&
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328
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P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

November 9, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

NOV 30 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

THE CLAIM		
ITI Man™	When your patients ask about sexual performance, offer a safe, scientifically studied, multiple pathway solution set shown to increase libido, performance and wellness in men and women.*	MacaPure (Lepidium meyenii), Yohimbe (Pausinystalia yohimbe) standardized to contain 6% yohimbine, Rhodiola Rosea Extract 3% rosavins, Horny Goat Weed (Epimedium brevicorum) standardized to contain 10% icariin, Panax ginseng root extract standardized to contain a minimum of 7% ginsenosides, Tongkat Ali (Eurycoma longifolia) LJ100

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

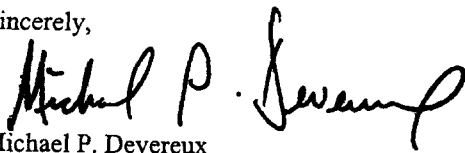
Date: 11/9/04

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer